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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,418	08/20/2003	Bob G. Sanders	D6150CIP/D	6977

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EXAMINER	
MAIER, LEIGH C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,418	SANDERS ET AL.	
	Examiner	Art Unit	
	Leigh C. Maier	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *9-13 and 21-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,14-20 and 26-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/29/05, 6/20/05*, 3/1/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of "neoplastic disease" as the disease species to be examined in the reply filed on August 16, 2006 is acknowledged. It is noted that Applicants state that they elect "examination of claims directed to the use of the indicated compounds for the treatment/*prevention* of 'neoplastic disease.'" (emphasis added) It appears that the methods are limited "treatment," and the claims are construed as such.

Claims 1, 14, 26 and 29 have been amended. Claims 31-84 are newly added. Claims 9-13 and 21-24 are withdrawn as being drawn to a non-elected invention. The examiner notes that Applicant has designated claim 20 as being withdrawn. However it is, in fact, drawn to the treatment of neoplastic disease and is included in the claims under examination.

Claim Rejections - 35 USC § 112 – 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-8, 26, 28, 31-33, 35, 37, 39, 41, 49, 52, 54, 56, 58-60, 62, 64, 66, 68, 76, 79, 81 and 83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The definition for R^4 has been amended to included "hydrogen" in the definition. The examiner finds no support for R^4 being hydrogen.

Claims 1-8, 14-20 and 26-84 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of colon and prostate cancer in a patient in need thereof, does not reasonably provide enablement for the general treatment of cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims without undue experimentation.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);
(2) The amount of direction or guidance presented;
(3) The presence or absence of working examples of the invention;
(4) The nature of the invention;
(5) The state of the prior art;
(6) The relative skill of those in the art;
(7) The predictability or unpredictability of the art; and
(8) The breadth of the claims.

The claims are drawn to methods of cell proliferative disease wherein the method is currently restricted to the treatment of neoplastic disease. The treatment of neoplastic disease comprises the treatment of all cancer, which encompasses a vast range of diseases. Furthermore, although the skill level in this art would be high, it remains the fact that many types of cancer remain intractable.

The examiner notes that Applicant has disclosed *in vitro* data tabulated for a number of compounds with a number of cell lines. However, out of 32 compounds in the table, 14 of them

are disclosed as having no activity and/or not tested. Furthermore, of the ones that are tested, the effectiveness is sporadic. Applicant does have animal testing for breast, colon and prostate cancer. The results for colon and prostate appear to be comparable to accepted treatments for these diseases. However, the effectiveness in breast cancer appears to be much less than taxol, so it is not clear that these data support effectiveness for the treatment of this disease. Additionally, cell line testing is not a reliable guide for *in vivo* treatment since such testing has historically failed to produce a number of compounds having a wide spectrum of tumor activity. As Monks (Anti-Cancer Drug Design, 1997) teaches, "mere detection of anti-proliferative activity is not enough to engender excitement." Even after the filing date of the instant application, broad extrapolation of *in vitro* testing to *in vivo* effectiveness remains problematic. See for example Balis (JNCI, 2002). Even determining the appropriate animal model is not routine. See for example Kerbel (Cancer and Metastasis, 1999).

For the reasons set forth above, it appears that one of ordinary skill would require undue experimentation in order to use the present invention commensurate with the scope set forth in the instant claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claims because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 14-20 and 26-84 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-16 of U.S. Patent No. 6,645,998.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of '998 recite the treatment of cell proliferative disorders, including neoplastic disease by the administration of a genus of compounds encompassed by the genus

used in the instant method. It would have been obvious to one of ordinary skill in the art at the time the invention was made to select cancer from the claimed cell proliferative disorders and use any of the species recited in the claims to administer for treatment thereof.

Claims 1-8, 14-20 and 26-84 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-65 of copending Application No. 10/695,275. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '275 recite a method for inhibiting the growth of tumor cells by administration of a genus of compounds encompassed by the instant claims. The use of any of the recited species would anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Wednesday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

Leigh C. Maier

Leigh C. Maier
Primary Examiner
October 26, 2006